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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,147	02/25/2002	Peng Cho Tang	038602-1329	1170
22428	7590	04/14/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			WRIGHT, SONYA N	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,147	Applicant(s) TANG ET AL.	
	Examiner Sonya Wright	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,9-12,15,16 and 18-22 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,5,9-12 and 15 is/are allowed.
- 6) ☒ Claim(s) 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0304</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This action is in response to Applicant's amendment filed 1-27-04. Claim 3 has been canceled. Claim 1 has been amended. Claims 1, 2, 4, 5, 9-12, 15, 16, 18-22, and 24 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

Claims 16 and 18-22 are drawn to a method for treating a protein kinase related disorder in an organism.

2) State of the prior art.

On page 1, lines 29-30 and page 2, lines 1-2 of the specification, Applicants indicate that abnormal protein kinase activity has been related to a host of disorders, ranging from relatively non-life threatening diseases such as psoriasis to extremely virulent diseases such as glioblastoma. On page 6, lines 8-9 of the specification, Applicants indicate that attempts have been made to identify small molecules that act as protein kinase inhibitors. On page 6, lines 25-29, Applicants indicate that their invention is drawn to a family of novel pyrrole substituted 2-indolinone compounds which exhibit PK modulating ability. However, the prior arts do not indicate that the instant compound is useful in treating all protein kinase related disorder.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

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Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for treating all disorders related to protein kinase.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that “ a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treatment of all disorders related to protein by the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the art pertaining to protein kinase related disorders.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art

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would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The specification provides little guidance regarding the use of the instant compound in treating all forms of protein kinase related disorders. Applicant provides information on biochemical and pharmacotherapy on page 31, lines 19-29, pages 32-39 in their entirety, and page 40, lines 1-7.

Applicant does not provide evidence that the instant compound is useful in treating all forms of disorders related to protein kinase. The guidance is limited because various disorders related to protein kinase have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol.

6) Existence of working examples.

The specification provides limited working examples on pages 41-47 in their entirety. However, the limited working examples do not support that the instant compound is useful in treating all forms of disorders related to protein kinase.

7) Breadth of claims.

Claims 16 and 18-21 are extremely broad due to the large number of disorders related to protein kinase. Applicant has not shown support that the instant compound is useful in treating all forms of disorders related to protein kinase.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

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Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating all disorders related to protein kinase, with no assurance of success.

These rejections can be overcome by Applicant listing in the claims which disorders related to protein kinase can be treated by the instant compounds. Any diseases which are listed in the claims should be supported in the specification with biological data.

Specification

The disclosure is objected to because of the following informalities: The graphs on pages 227 and 228 of the specification do not comply with 37 CFR 1.58(a). It is suggested that Applicant delete the graphs on pages 227 and 228 of the specification and submit the graphs as separate drawing sheets per 37 CFR 1.81. If Applicant submits the graphs as separate drawing sheets, it is requested that Applicant insert a description of said drawing sheets in the specification.

Appropriate correction is required.

Allowable Subject Matter

Claims 1, 2, 4, 5, 9-12, and 15 are allowable over the prior art of record.

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PTO-1449 page 2 of 6 was not previously signed and dated by the Examiner. Therefore, a copy of PTO-1449 page 2 of 6 has been signed and dated by the Examiner and is attached.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (571) 272-0711. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The Official fax phone number for this Group is (703) 872-9306.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by

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the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to Technology Center 1600 at (571) 272-1600.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

April 8, 2004